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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,596	06/26/2006	Gary Falwell	B1075.70032US00	4569

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EXAMINER
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DELLA, JAYMI E

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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09/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,596	<b>Applicant(s)</b> FALWELL ET AL.	
	<b>Examiner</b> JAYMI DELLA	<b>Art Unit</b> 3739	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43, 74 and 95 is/are pending in the application.
- 4a) Of the above claim(s) 11, 16-43, 74, and 95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/2/2005, 08/14/2006, 09/26/2008</u>                         | 6) <input type="checkbox"/> Other: _____                          |



## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of **Group I**, claims 1-15 and **Set I: Species A**, claims 1-43, 74, 95 in the reply filed on 8/07/2009 is acknowledged.
2. The examiner sought further clarification on election of the remainder of the species sets during a telephone conversation with Melissa Beede on August 18, 2009, which resulted in a provisional election without traverse to prosecute the invention of:

**Set I: Species A**, claims 1-43, 74, 95

**Set II: Species A**, claims 1-43, 74, 95

**Set III: Species A**, claims 1-43, 74, 95

**Set IV: Species B**, claims 1-43, 74, 95

**Set V: Species A**, claims 1-43, 74, 95

**Set VI: Species B**, claims 1-15, 74, 95

**Sub-Set I: Species A**, claims 1-10, 12-15, 74, 95

**Sub-Set II: Species A**, claims 1-15, 74, 95

**Sub-Set III: Species B**, claims 1-15, 74, 95

**Set VII: Species B**, claims 1-43, 74, 95

**Sub-Set I: Species B**, 1-15, 74, 95

**Sub-subset I: Species A**, claims 1-15, 74, 95

**Sub-subset II: Species A**, claims 1-15, 74, 95

**Set VIII: Species B**, claims 1-43, 74

**Sub-Set I: Species A**, claims 1-43, 74

**Sub-Set II: Species A**, claims 1-43, 74

**Set IX: Species A**, claims 1-43, 74

**Sub-Set I: Species B**, claims 1-43, 74

**Set X: Species A**, claims 1-43, 74

**Set XI: Species A**, claims 1-43, 74

**Set XII: Species A**, claims 1-43, 74

**Set XIII: Species A**, claims 1-43, 74

**Set XIV: Species A**, claims 1-43, 74, 95

3. Therefore, only claims readable on all elected species that fall within the claims readable for the elected Group are examined. Thus, claims 1-10 and 12-15 are examined below, and claims 11, 16-43, 74, and 95 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Affirmation of this election must be made by applicant in replying to this Office action.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Specification***

5. The disclosure is objected to because of the following informalities: replace "nitinol" with --Nitinol—on Page 26, Line 4 and Page 36, Line 18. Appropriate correction is required.
6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

7. Claim 15 is objected to because of the following informalities: replace "nitinol" with --Nitinol--. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 8, 10, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. The term "approximately" in claims 8, 10 and 13 is a relative term which renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

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of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The parameter rendered indefinite by the use of the term “approximately” is the bend bias angle of the proximal end of the tip assembly.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**14. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (U.S. Patent No. 5,755,760) in view of Jaraczewski et al. (U.S. Patent No. 5,938,694, cited in IDS).**

15. Concerning **claims 1 and 14**, Maguire et al. disclose **an electrophysiology catheter** (electrophysiology catheter as shown in Fig. 612B, where Fig. 12A-B depict employing the deflection mechanism of the catheter illustrated in Fig. 6-11) **comprising:**

**a handle having a distal end and a proximal end** (handle 608; Fig. 12A), **the handle including an actuator** (actuator comprises is taken to be any one of control knobs 610, 612, 614 and 616; Fig. 12A);

**a flexible shaft having a proximal end and a distal end and a longitudinal axis that extends along a length of the shaft, the proximal end of the shaft being attached to the distal end of the handle** (shaft 600 is flexible because Maguire et al. state that distal end 602 and intermediate section 604 are provided with internal tension wires operative as illustrated in Fig. 6-11, where the tube forming the distal section is at least three times as flexible as the tube forming the intermediate section and the tube forming the intermediate section is at least three times as flexible as the main catheter shaft; Column 8, Lines 6-9.),

**a tip assembly having a proximal end and a distal end** (distal tip 602; Fig. 12A), **the proximal end of the tip assembly being attached to the distal end of the shaft** (distal tip 602 is directly connected to intermediate shaft section 604, which is directly connected to shaft 600; Fig. 12A); **and**

**a cable, attached to the actuator and the tip assembly, that extends through the shaft, the cable being adapted to change an orientation of the tip assembly from the first orientation in response to movement of the actuator** (the cable is taken to be any one of the following: core wire 556 connected to actuator control knob 612 that deflects/twists intermediate section 450 as illustrated in Fig. 8; or internal sliding core wire connected to actuator control knob 616 that varies the arc curvature of the distal section 460 as illustrated in Fig. 12b; Column 7, Lines 46-47 and Column 10, Lines 1-21).

Maguire et al. fail to disclose the tip assembly including a wire formed of a superelastic material and shaped to bias the tip assembly in a first orientation. However, Jaraczewski et al. disclose an electrophysiology catheter as shown in Fig. 1 and 5 that has a core (14) extending from core transition region (13) to tip electrode (10) (Column 5, Lines 4-5). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a superelastic spring material because it is very resilient and has a good spring memory for its prior shape, even when highly flexed as taught by Jaraczewski et al. (Column 5, Lines 24-25).

16. Concerning **claims 2 and 4-5**, Jaraczewski et al. disclose that the tip (24) is made so that it assumes a coiled conical shape that when in an unconstrained,

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deployed position, the curved shape has one or more curved regions curving more than 360 degrees (Column 5, Lines 28-29; Fig. 1-2; and Claim 1). Thus, the superelastic wire is shaped to bias the distal end of the tip in a first orientation that is in an arcuately curved shape spanning at least three hundred and sixty degrees and having a bias radius of curvature as illustrated in Fig. 1-2.

Maguire et al. disclose the internal sliding core wire connected to actuator control knob (616) that capable of varying the arc curvature of the distal section (460) to be larger or smaller than the bias radius of curvature as illustrated in Fig. 12b (Column 10, Lines 1-21).

17. Concerning **claim 3**, Maguire et al. as modified by Jaraczewski et al. disclose substantially all the limitations of the claim(s) except the wire having a radius of curvature smaller than or equal to a radius of curvature of the cable. It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to place wire and cable in these locations, since applicant has not disclosed that the location of the cable or wire within the distal tip solves any stated problem or is for any particular purpose and it appears that the invention would perform equally as well with the cable and wire in any location within the distal tip as it is preformed to a certain shape and the cable is capable of changing that shape.

18. Concerning **claim 6**, Maguire et al. as modified by Jaraczewski et al. disclose substantially all the limitations of the claim(s) except the cable having a radius of curvature smaller than or equal to a radius of curvature of the wire. It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the

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invention was made to place wire and cable in these locations, since applicant has not disclosed that the location of the cable or wire within the distal tip solves any stated problem or is for any particular purpose and it appears that the invention would perform equally as well with the cable and wire in any location within the distal tip as it is preformed to a certain shape and the cable is capable of changing that shape.

19. **Claim 7** is rejected upon the same rationale as that applied to claim 4.

20. Concerning **claim 8**, Maguire et al. fail to disclose the wire being shaped to bias the proximal end of the tip assembly in a first orientation that includes a bend having a bias angle of approximately ninety degrees relative to the longitudinal axis of the shaft. However, Jaraczewski et al. disclose the superelastic core (14) is shaped to bias the proximal end of the tip assembly in a first orientation with a bend of approximately ninety degrees relative to the longitudinal axis of the shaft as Fig. 1 and 3D. At the time of the invention, it would have been obvious to bias the bend at ninety degrees in order to provide the benefit of three-dimensional area array of electrodes that engage a portion of the chamber wall of the heart so that a relatively large surface area of the heart can be mapped precisely and in a relatively short time span as taught by Jaraczewski et al. (Column 3, Lines 42-47), and also to provide the benefit of deflecting the probe tip to another area of the heart versus repositioning the entire probe to a second area.

Maguire et al. disclose core wire (556) connected to actuator control knob (612) that deflects/twists intermediate section (450) as illustrated in Fig. 8, capable of

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changing the bend of the proximal end of the tip assembly to an angle smaller than the bias angle (Column 7, Lines 46-47).

21. Concerning **claim 9**, Maguire et al. as modified by Jaraczewski et al. disclose substantially all the limitations of the claim(s) except the wire disposed in an inner portion of the tip assembly and the cable disposed in an outer portion of the tip assembly. It would have been an obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to place wire and cable in these locations with respect to the angle of the bend of the proximal end of the tip assembly, since applicant has not disclosed that location of the cable and wire solves any stated problem or is for any particular purpose and it appears that the invention would perform equally as well with the cable and wire in either location.

22. Concerning **claim 10**, Maguire et al. as modified by Jaraczewski et al. disclose the wire being shaped to bias the proximal end of the tip assembly in a first orientation that includes a bend having a bias angle relative to the longitudinal axis of the shaft as explained in the rationale applied to claim 8.

Maguire et al. disclose core wire (556) connected to actuator control knob (612) that deflects/twists intermediate section (450) as illustrated in Fig. 8, capable of changing the bend of the proximal end of the tip assembly to an angle of approximately ninety degrees relative to the longitudinal axis of the shaft (Column 7, Lines 46-47).

23. **Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (U.S. Patent No. 5,755,760) in view of Jaraczewski et al. (U.S.**

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**Patent No. 5,938,694, cited in IDS), as applied to claim 1 above, in further view of Rashidi (U.S. Patent No. 6,728,563).**

**24.** Concerning **claim 12**, Maguire et al. as modified by Jaraczewski et al. fail to disclose the wire shaped to bias the distal end of the tip assembly in a linear orientation. However, Rashidi discloses an electrophysiology catheter that has an initial linear orientation of its distal tip (10) as illustrated in Fig. 5 and 9 (Column 5, Line 12-14). At the time of the invention, it would have been obvious to one of ordinary skill in the art to bias the tip assembly in a linear orientation in order to facilitate easier insertion into a guide catheter for placement into the target area as taught by Rashidi (Column 5, Lines 7-10).

Maguire et al. disclose the internal sliding core wire connected to actuator control knob (616) that capable of varying the arc curvature of the distal section (460) to be larger or smaller than the bias radius of curvature as illustrated in Fig. 12b (Column 10, Lines 1-21).

**25.** Concerning **claim 13**, Maguire et al. as modified by Jaraczewski et al. fail to disclose the wire shaped to bias the distal end of the tip assembly in a linear orientation. However, Rashidi discloses an electrophysiology catheter that has an initial linear orientation of its distal tip (10) as illustrated in Fig. 5 and 9 (Column 5, Line 12-14). At the time of the invention, it would have been obvious to one of ordinary skill in the art to bias the tip assembly in a linear orientation in order to facilitate easier insertion into a guide catheter for placement into the target area as taught by Rashidi (Column 5, Lines 7-10).

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Maguire et al. disclose core wire (556) connected to actuator control knob (612) that deflects/twists intermediate section (450) as illustrated in Fig. 8, capable of changing the bend of the proximal end of the tip assembly to an angle smaller than the bias angle (Column 7, Lines 46-47).

**26. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maguire et al. (U.S. Patent No. 5,755,760) in view of Jaraczewski et al. (U.S. Patent No. 5,938,694, cited in IDS), as applied to claims 1 and 14 above, in further view of Keane (U.S. Patent No. 6,607,520).**

**27.** Concerning **claim 15**, Maguire et al. in view of Jaraczewski et al. fail to disclose the wire being formed of Nitinol. However, Keane discloses an electrophysiology catheter system (100) with a distal end ablation element (102) forming a variety of geometries (Column 3, Lines 42, 49-50). The ablation member (102) is formed of superelastic shape memory material Nitinol (Column 4, Lines 16-17). At the time of the invention, it would have been obvious to one of ordinary skill in the art to use Nitinol as it provides the benefit of a shape memory material that can be plastically deformed from a first shape at a low temperature and upon heating the material to a higher temperature, the material returns to the first shape as taught by Keane (Column 4, Lines 22-25).

### ***Conclusion***

**28.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Avitall (U.S. Patent No. 6,327,905, cited in IDS) discloses an electrophysiology vascular catheter with a dual-wire and one-wire system for vertical and lateral deflection of the distal tip.

Tu et al. (U.S. Patent No. 6,308,090) disclose an electrophysiology catheter with a pre-shaped, deflectable distal tip portion both in the radius of curvature and bend of the proximal end of the distal tip.

Stewart et al. (U.S. Patent No. 6,325,797) disclose an electrophysiology catheter with an arcuate distal tip.

Bowe et al. (U.S. Patent No. 6,771,996) disclose an electrophysiology catheter with an arcuate distal tip and a deflectable bend in the proximal end of the distal tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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